Title: Procedure for Determining Which Projects Need Verification from Sources Other Than the Investigators That No Material Changes Have Occurred since Previous IRB Review
Standard Operating Procedure: #15
Department: Human Research Protection Program/Institutional Review Board
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Subject: Continuous Quality Improvement

Policy:
To maintain excellence in the protection of human subjects and to meet Department of Energy Human Subjects' standards, as well as the regulatory standards as promulgated by the Health and Human Services, Office for Human Research Protections (OHRP), a successful monitoring program is essential. At Lawrence Livermore National Laboratory (LLNL), the Continuous Quality Improvement (CQI) program serves to keep investigators cognizant of rules, to correct procedural errors, and most importantly, to increase protections for subjects enrolled in research projects. CQI procedures include assessing investigator compliance with the IRB, assessing the IRB review process, obtaining assurance that the investigator has been following the protocol (as approved), and inspecting study records and documentation.[1]

A system of regular, not for cause, objectively chosen monitoring visits is an indicator of quality or lack thereof, a communication tool, and a process that raises standards. Audits may also be initiated in response to protocol amendments, continuing reviews, previous investigator noncompliance, or reviewer questions and concerns.

The Chair and Administrator of the IRB will conduct such audits. Observations and reports are submitted to the investigator and researchers. The IRB may not be notified of findings unless noncompliance issues put subjects at an increased level of risk.

Under federal regulations, the IRB has the right to monitor adherence to IRB approved research protocols. Therefore, the IRB/Human Research Protection Program is creating an oversight process that does not end with approval of a research protocol. The LLNL CQI program seeks to fulfill its commitment to comply with federal regulations as declared in the Federalwide Assurance, and to protect human research subjects.

Reference:
45 CFR 46

[1] "Not for Cause" Audits: The IRB Chair and Administrator conduct internal assessments to improve the overall program, assure researcher adherence to IRB policies, federal regulations, and the protocol. Outcomes include identifying and correcting noncompliance, working with researchers to adopt best practices, and offering training to researchers and staff.